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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/993,696	12/18/1997	DAVID J. SCHANZLIN	251692002821	5525

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EXAMINER	
WILLSE, DAVID H	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/993,696	SCHANZLIN ET AL.	
	Examiner	Art Unit	
	Dave Willse	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *86-93* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *86-93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4-7-05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 86-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herrick, US 4,781,187, in view of Siegel, DE 37 19 177 A1. Herrick employs donor corneal tissue (inherently comprising natural polymers such as collagen and mucopolysaccharide) but lacks any mention of a *synthetic* polymer for the implant material (column 3, lines 41-49). Siegel teaches a replacement human cornea comprising at least one synthetic polymer, the material promoting corneal endothelial cell adherence and growth on the surface, being permeable to ions and nutrients, and being severable to the required size (Derwent abstract). Substituting such a

material for the Herrick invention would have been obvious in order to provide desirable material properties, reduce the risk of disease transmission, ensure the availability of materials, and so on, especially in the absence of any advantage or criticality in the instant disclosure of synthetic polymers over natural polymers (*In re Kuhle*, 188 USPQ 9; *Ex parte Clapp*, 227 USPQ 972, 973). In fact, the Applicant's specification states that synthetic or natural polymers may be used (page 1, lines 18-19; page 17, lines 15-17) and even includes collagen as a possible material (original claim 63). Regarding claims 88 and 89, a radius of curvature within the prescribed ranges would have been immediately obvious from the intended use of the device, as best illustrated by Figures 3, 4, 7, and 9, of Herrick. Regarding claims 91-93, although Herrick specifies typical dimensions "on the order of a length of 3.5 to 4.0 millimeters" (column 3, lines 52-56), lengths as low as 2.0 millimeters would have been obvious in order to accommodate experimentation or practice on rabbits and other small animals or to minimize the length of the corneal incision.

Claims 86-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Herrick, US 4,781,187, in view of Silvestrini, WO 95/03747 A1. Silvestrini teaches corneal inserts which "may be of one or more synthetic or natural polymers" (page 3, line 32), which "may be used in isolation, in isolated multiples, in cooperative multiples, or as segments in a larger assemblage encircling at least a portion of the cornea" (page 3, lines 28-31), which advantageously may be provided with "a measure of lubricity" (page 5, lines 5-7; page 11, line 19 et seq.), and which may be trimmed to a shorter length (page 20, lines 24-27), so there does not appear to be any concern with implant migration. Using synthetic materials disclosed by Silvestrini for the Herrick radial inserts would thus have been obvious for reasons set forth above.

Claims 86-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gonchar et al., "Interlayer Refraction Tunnel Keratoplasty in Correcting Myopia and Astigmatism", in view of Siegel, DE 37 19 177 A1, or Silvestrini, WO 95/03747 A1. The implants being of a synthetic polymer would have been an obvious material variant for reasons provided above with respect to the Herrick patent. Regarding claims 88 and 89, values within the specified ranges would have been immediately obvious from the purpose of the implants (Figure 3 of Gonchar et al.). Regarding claims 91-92: page 4, line 16, of the English translation of Gonchar et al. Regarding claim 93, an implant having a length of 2.0 mm or less would have been obvious in order to accommodate a variety of eye sizes (e.g., page 2, lines 3-4, of said translation) and refractive disorders.

The Declaration under 37 CFR 1.132 filed April 7, 2005, is insufficient to overcome the rejection of claims 86-93 based upon Herrick and Gonchar et al. as set forth in the last Office action because at the time of the present invention there had been disclosed in the prior art suitable materials comprising at least one synthetic polymer and having an appropriate modulus of elasticity and/or corneal cell growth and adherence promoting characteristics, as demonstrated by the grounds of rejection applied above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is 571-272-4762. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dave Willse
Primary Examiner
Art Unit 3738